REMARKS

Cancellation of Claims

Claim 11 is canceled herein without prejudice, waiver, or disclaimer. Applicants take this action merely to reduce the number of disputed issues and to facilitate early allowance and issuance of other claims in the present application. Applicants reserve the right to pursue the subject matter of those canceled claims in a continuing application, if Applicants so choose, and do not intend to dedicate any of the canceled subject matter to the public.

Response To Rejections

Response To Claim Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 11 has been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite because "Claim 1, from which claim 11 depends, already defines the image acquisition system as a flow cytometer." *Office Action* at 2-3. Applicants respectfully traverse. Specifically, the Office Action admits the following:

> Applicants should note that the claims recite "comprising" language, which is open language that allows for the presence of components in addition to those explicitly recited. Nothing in the instant claims excludes the presence of an additional detector or imaging instrument.

Office Action at 6. Therefore, assuming *arguendo* that the above-cited statement about claim 1 is accurate, then the recitation of the imaging acquisition system being a camera in dependent claim 11 is not indefinite. Nevertheless, to advance prosecution and facilitate early allowance of the claims, Applicants cancel claim 11 herein, as suggested by the Office.

Applicants wish to clarify that the foregoing amendment is cosmetic in nature and is not made as a condition for obtaining a patent. Applicant further submits that this amendment is non-narrowing and, pursuant *to Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002), no prosecution history estoppel arises from this amendment. *See also Black & Decker, Inc. v. Hoover Svc. Ctr.*, 886 F.2d 1285, 1294 n. 13

(Fed. Cir. 1989); *Andrew Corp. v. Gabriel Elec., Inc.*, 847 F.2d 819 (Fed. Cir. 1988); *Hi-Life Prods. Inc. v. Am. Nat'l Water-Mattress Corp.*, 842 F.2d 323, 325 (Fed. Cir. 1988); *Mannesmann Demag Corp. v. Eng'd. Metal Prods. Co., Inc.*, 793 F.2d 1279, 1284-1285 (Fed. Cir. 1986); *Moeller v. Ionetics, Inc.*, 794 F.2d 653 (Fed. Cir. 1986).

Response To Claim Rejections Under 35 U.S.C. §103

(a) Claims 1-6, 8, 11, and 25-27

Claims 1-6, 8, 11, and 25-27 have been rejected under 35 U.S.C. Section 102(b) as allegedly anticipated by *Yaremko et al.* in view of *Layne et al.* Although the Office Action admits that "Yaremko et al fail to teach a flow cytometer in the system for image aquisitioning," the Office Action also states:

> *Layne et al.* is directed to an apparatus for automated testing of biological specimens *Layne et al.* teach that image acquisitioning in automated analyses allows detection of target individual cells and allows the collection of data to be observed by the user later. *Layne et al.* teach that flow cytometry is suitable for image acquisition (col. 14, lines 14-19; col. 17, lines 34-39). It would have been obvious to one of ordinary skill in the art to modify the *Yaremko et al.* reference by substituting the camera imaging system for a flow cytometry imaging system, as taught by *Layne et al.* In testing of blood specimens, such a modification would allow the user to detect and analyze individual blood cells.

Office Action at 4. Applicants respectfully traverse, at least with respect to the assertion regarding *Layne et al.* It is well established law that, for a proper rejection of a claim under 35 U.S.C. §103 as being obvious based upon a combination of references, the cited combination of references must disclose, teach, or suggest, either implicitly or explicitly, all elements/features/steps of the claim at issue. *See, e.g.*, *In Re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 208 U.S.P.Q. 871, 881 (C.C.P.A. 1981).

The combination of *Yaremko et al.* with *Layne et al.* do not teach or suggest the features of independent claims 1 and 25.

For example, independent claim 1, as amended, recites the following:

1. An immunological assay system, comprising:

a filter vessel capable of containing an assay sample;

an incubator in which the filter vessel may be placed, wherein the incubator houses the filter vessel while the assay sample and one or more reagents react;

a sample separation system in close proximity to the incubator, wherein the sample separation system is designed to separate the assay sample and the reagents into various components;

an image acquisition system in close proximity to the sample separation system, wherein the image acquisition system is ***composed of*** a flow cytometer, the flow cytometer being ***designed to detect the presence of interactions between the components and reagents of the assay mixture***, wherein said interactions are evidenced by at least one of agglutinations and antigen-antibody interactions; and

a robotic pipettor including a robotic arm within reaching distance of the filter vessel, the incubator, the sample separation system and the image acquisition system, wherein the robotic pipettor is designed to transfer the sample or the reagents between the filter vessel, incubator, the sample separation system and the image acquisition system.

Also, as admitted by the Office, *Yaremko et al.* failed to teach a flow cytometer as an imaging acquisition system. *Layne et al.* also do not cure this deficiency of *Yaremko et al.*

When describing their image acquisition apparatus at column 14, lines 14-19, *Layne et al.* simply disclose that "the image acquisition and analysis SLM 224 detects individual HIV-infected cells within cell monolayers, and collects observable data. In one embodiment, the image acquisition and analysis SLM comprises a *digital image analysis system* ***and*** *motorized microscope stages* ...." *Layne et al.* at col. 14, lines 14-19 (emphasis added). *Layne et al.* couple their digital image analysis system with motorized microscope stages. No where in the specification do *Layne et al.* teach that its digital image analysis system is in fact composed *only* of a flow cytometer.

With respect to the claim language that includes a flow cytometer, the claim language reads as follows: "*multiple* detector instruments which are selected for the same biological specimen, in which are at least *two* of a digitized microscope, a colorimeter, a flow cytometer, and a scintillation detector." *Layne et al.* at claims 12 and 23 (Emphasis

added). Again, *Layne et al.* require, in addition to the flow cytometer, another type of detector instrument to analyze the biological specimen.

Claim 1 has been amended herein to recite that "the image acquisition system is ***composed of*** a flow cytometer." (Emphasis added). By using the closed expression "composed of", Applicants submit that the image acquisition system of claim 1 excludes the combination digital analysis system of *Layne et al.* Therefore, for at least this reason, Applicants respectfully request that the rejection of claim 1 be withdrawn.

(ii) Claims 1 and 25

In addition to this difference, the configuration of the flow cytometer recited in claims 1 and 25 is not taught or suggested by the prior art. Flow cytometers are automated instruments that traditionally have been used to quantitate properties of *single* cells, *one cell at a time*. The Office Action itself admits with respect to *Layne et al.* that "Layne teaches that the image acquisition and analysis SLM detects *individual cells* within cell monolayers...." *Office Action* at 6 (emphasis added). In contrast, claim 1 recites the following: "wherein the image acquisition system is a flow cytometer and is designed to detect the presence of interactions between the components and reagents of the assay mixture, *wherein said interactions are evidenced by agglutinations*." *Claim 1*, as amended (emphasis added). Thus, the flow cytometer as recited in claim 1 does not necessarily require single cells, but rather is being used to detect agglutinations of cells.

The Office Action states that Applicants' argument that *Layne et al.* not disclosing an image acquisition system that is "able to detect agglutination interactions between the components and reagents of the assay mixture... is directed to the function of the image acquisition system. Functional language does not limit the claims sufficiently to impart patentability." *Office Action* at 6. Applicants respectfully traverse. In particular, Applicants note that the "designed to" language now inserted into independent claim 1 is not merely functional language, but should be construed as a structural feature of the system of claim 1. *See* MPEP 2173.05(g), last paragraph ("[T]he Court held that limitations such as 'members *adapted to* be positioned'... serve to *precisely define present structural attributes* of interrelated component parts of the claimed assembly. *In*

re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976)." (emphasis added)). Applicants submit that the feature of claim 1 "designed to detect the presence of interactions" precisely defines structural attributes of the flow cytometer that differentiate it from the flow cytometer disclosed in *Layne et al.*, and is not merely functional language. For at least this reason also, Applicants respectfully request that the rejection of claim 1 be withdrawn.

> Similarly, independent claim 25 has been amended to recite in part the following:
>
> wherein the flow cytometer is also ***configured to*** determine the presence of interactions between the sample and the reagent, wherein said interactions are evidenced as at least one of aggregated components and antigen-antibody interactions

Claim 25, as amended (emphasis added). The flow cytometer as recited in claim 25 is used to analyzed aggregated components, rather than single cells. Nothing in the cited references teach or suggest these features. Following the reasoning presented above with respect to claim 1, the feature of claim 25 "configured to detect the presence of interactions" precisely defines structural attributes of the flow cytometer that differentiate it from the flow cytometer disclosed in *Layne et al.* For at least this reason also, Applicants respectfully request that the rejection of claim 25 be withdrawn.

Hence the combination of *Yaremko et al.* in view of *Layne et al.* does not render claims 1 and 25 obvious. Applicants respectfully request that the rejection be withdrawn.

If independent claims 1 and 25 are allowable over the prior art of record, then their respective dependent claims 2-9, 12-24 and 26-28 are also allowable as a matter of law, because these dependent claims contain all features/elements of their respective independent claims. *See Minnesota Mining and Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299 (Fed. Cir. 2002). Additionally and notwithstanding the foregoing reasons for the allowability of claims 1 and 25, these dependent claims recite further features and/or combinations of features, as apparent by examination of the claims themselves, that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable in view of *Yaremko et al.* in view of *Layne et al.*

For example, as noted previously, *Yaremko et al.* do not teach the washer of dependent claim 2. *Layne et al.* do not cure this deficiency. Specifically, claim 2 recites

the following: "a washer, wherein the washer is designed to wash the assay sample while the sample is disposed within the filter vessel." The Office Action asserts that "[t]he fact that the washers of Yaremko et al may not be disclosed as functioning in the manner as Applicants' washers is insufficient to impart patentability to the claims." *Office Action* at 5-6. Applicants respectfully traverse. Applicants have clearly used the *structural not functional* language "designed to" in claim 2 with respect to the washer. Because the washer of claim 2 are structurally different (*i.e.*, designed different) from those of *Yaremko et al.*, Applicants respectfully request that the rejection of claim 2 be withdrawn.

(b) Claims 9 and 28 have been rejected under 35 U.S.C. Section 103(a) as purportedly being obvious over *Yaremko et al.* in view of *Franciskovich et al.* Specifically, the Office Action states:

> The disclosure of *Yaremko et al.* is described above. *Yaremko et al.* fail to teach a vacuum system for separating the sample.
>
> *Franciskovich et al.* teach an apparatus for separating samples into their constituents. The reference teaches that both centrifuges and vacuums provide good means for separating multiple samples into their base constituents simultaneously. See col. 2, lines 2-5-31. Thus, it would have been obvious to substitute the centrifuge assembly of *Yaremko et al.* with a vacuum assembly as disclosed by *Franciskovich et al.* to allow simultaneous separation of multiple samples and thus increase the sample processing time.

Office Action at 4-5. Applicants respectfully traverse on the grounds that *Yaremko et al.* in view of *Franciskovich et al.* do not teach or suggest all of the features of independent claims 1 and 25. In addition, because independent claims 1 and 25 are allowable, their dependent claims 9 and 28 should also be allowable.

(c) Claim 7 has been rejected under 35 U.S.C. Section 103(a) as purportedly being obvious over *Yaremko et al.* in view of *Datar*. Specifically, the Office Action states:

> The disclosure of *Yaremko et al.* is described above. *Yaremko et al.* fail to teach the particular filter materials recited in claim 7.
>
> *Datar* teaches efficient separation of cells, cellular materials and proteins. Specifically, *Datar* teaches separation devices such as bead columns. Further, *Datar* teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of *Yaremko et al.* These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

Office Action at 5. Applicants respectfully traverse on the grounds that *Yaremko et al.* in view of *Datar* do not teach or suggest all of the features of claim 7. In addition, because claim 7 depends from allowable claim 1, claim 7 should also be allowable. Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1-9 and 12-28 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,

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